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CleanImplant Foundation: Dental Implant Quality under Scrutiny

On-site SEM analysis of implants for dentists and demos for implant manufacturers at IDS 2021 in cooperation with Thermo Fisher Scientific

"Sterile packaged" does not mean an implant is necessarily free of contaminants. This disturbing realization is slowly dawning on dentists not only in Europe and the US. Exceeding 100.000 subscriptions on Facebook's CleanImplant site, the number of dentists worldwide intrigued by this revelation increased tenfold over the past two years.

Transparent Testing Procedure

At the International Dental Show IDS in Cologne coming up in September, the non-profit CleanImplant Foundation based in Berlin, Germany, once again showcases the quality check of dental implants using a scanning electron microscope. Installed exclusively for this event in Hall 10.2 in collaboration with Thermo Fisher Scientific and the 'Medical Materials Research Institute', the set-up provides full transparency of the Foundation's quality assessments.

Dentists and manufacturers alike can witness the meticulous and independent quality check of dental implants in detail, from start to finish. The open and public demonstration allows spectators to learn about the extent of factory-related contamination of sterile packaged implants, and most importantly, its direct consequences. The SEM unveils whether an implant meets the strict consensus-based CleanImplant Quality Guidelines, and dentists are encouraged to participate in finding out whether what they deem the implant system used in their practice is actually safe.

Dentists and Patients request Clarity

Ever since the "implant files" became public in the media, dentists' concerns about substandard medical products worldwide have grown immensely – and rightly so. Current study data exhibits that one out of three implant systems analyzed contains technically avoidable impurities. Contaminants include organic particles from the manufacturing process, plastic from packaging, and metallic particles of nickel, tungsten, iron, copper, and chromium, just to name a few. Despite the shocking discovery, all implants with significant impurities carried the CE mark or showed FDA clearance. When thoroughly analyzed, an unexpectedly large number of implant systems fail to keep their promise of delivering clean medical devices.

The sterile packaging does not change that either. This ultimately harms the patients and endangers every dentist as products with impurities cause poor clinical results, and upon failure, entail severe legal implications.

Clear the Stage for High-Quality Manufacturers

The CleanImplant Foundation has been coordinating worldwide quality assessment studies of dental implants with renowned universities for many years. Following a strict peer-review process, the Trusted Quality Mark is awarded to particularly clean implant systems only. To date, recipients awarded the quality seal include selected implant systems by Biotech Dental, Bredent Medical, BTI Biotechnologies, Camlog, Global D, medentis medical, MegaGen, Nobel Biocare, NucleOSS, Straumann, Sweden & Martina, and Zirkon Medical.

However, before the coveted Trusted Quality Mark is awarded, each implant system is tested based on five randomly selected samples from multiple batches. With at least two of these samples purchased from anonymous blind-shopping or provided directly from dental practices as they would be used on patients, this procedure avoids a possible pre-selection of testing samples by the manufacturer. Samples must comply with the strict thresholds set in a consensus process by renowned scientists of the Foundation's Scientific Advisory Board, such as Tomas Albrektsson, Ann Wennerberg, Hugo De Bruyn, Michael Norton, Florian Beuer, and others. Simply technical cleanliness, however, does not suffice for the time-limited award. After additional proof of successful clinical documentation, the peer review process will determine if an implant system meets the quality criteria and thus receives the award. In order to remain relevant and up-to-date, this process must then be repeated every two years to refresh the quality seals lifecycle. As of this year, dentists can showcase their commitment to dental excellence and clean implantology as a so-called 'CleanImplant Certified Dentist', ultimately rewarding their patients' trust with added backed-up confidence in their chosen implant.

Dental trade show visitors and manufacturers are free to book appointments in advance for the live demo at the SEM: IDS Hall 10.2 | P032.

For more information, see www.cleanimplant.org or www.facebook.com/cleanimplant.

About the partners:

The independent **CleanImplant Foundation** was founded as a non-profit organization in Berlin in 2016. In cooperation with renowned universities, the foundation regularly coordinates worldwide quality assessment studies of dental implants and awards the "Trusted Quality Mark" to particularly clean types following a strict peer review process. CleanImplant certifies dental surgeons/implantologists as well as dental centers that use demonstrably clean implants, i.e. implants that are not contaminated with foreign particles.

Further information: www.cleanimplant.org

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The **medical materials research institute - mmri.berlin** is a DIN EN ISO/IEC 17025:2018 accredited testing laboratory located in Berlin-Adlershof, Germany. The laboratory specializes in the analysis of dental implants in a clean room environment and produces independent test reports on surface cleanliness. Using energy dispersive X-ray spectroscopy (EDX) and time-of-flight secondary ion mass spectrometry (ToF-SIMS), avoidable residues on medical devices can not only be chemically characterized. The methods also provide valuable information about the cause of the contamination and ways to avoid it. www.mmri.berlin

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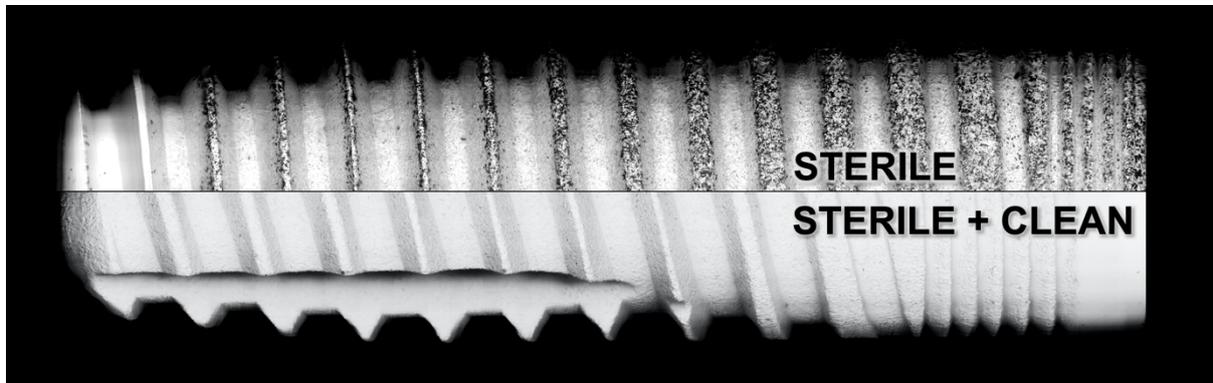


Fig. 1:
Full-size high-resolution SEM image mapping of two original-packaged implants, both samples with FDA clearance and ready to use for patients.



Fig.2:
SEM testing station at the IDS

Fig.3:
Dr. Duddeck, dentist and founder of the CleanImplant Foundation, explains the dangers of contaminated medical devices.